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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,472	LI ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21 and 23-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 and 23-44 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1-21, 25-29, drawn to methods of using an agent that promotes elastin signaling, wherein the agent is a nucleic acid.

Group 2, claims 1-21, 23-29, drawn to methods of using an agent that promotes elastin signaling, wherein the agent is a peptide, a polypeptide or a peptidomimetic.

Group 3, claims 1-21, 25-29, drawn to methods of using an agent that promotes elastin signaling, wherein the agent is a small organic molecule.

Group 4, claims 1-21, 25-29, drawn to methods of using an agent that promotes elastin signaling, wherein the agent is an antisense oligonucleotide.

Group 5, claims 1-21 and 25-29, drawn to methods of using an agent that promotes elastin signaling, wherein the agent is a RNAi construct.

Group 6, claims 1-21 and 25-29, drawn to methods of using an agent that promotes elastin signaling, wherein the agent is a ribozyme.

Group 7, claims 1-21 and 25-29, drawn to methods of using an agent that promotes elastin signaling, wherein the agent is an antibody.

Group 8, claims 30-31, 34-35, drawn to a method of screening to identify and/or characterize an elastin activator that promotes elastin signaling in smooth muscle cells.

Group 9, claims 32-33, drawn to an agent identified by the screening method, that increases actin stress fiber formation in smooth muscle cells.

Group 10, claims 32-33, drawn to an agent identified by the screening method, that increases expression of vinculin in smooth muscle cells.

Group 11, claims 32-33, drawn to an agent identified by the screening method, that increases focal adhesion formation in smooth muscle cells.

Group 12, claims 32-33, drawn to an agent identified by the screening method, that inhibits dedifferentiation of smooth muscle cells.

Group 13, claims 32-33, drawn to an agent identified by the screening method, that promotes actin polymerization in smooth muscle cells.

Group 14, claims 32-33, drawn to an agent identified by the screening method, that increases the ratio of F:G actin in smooth muscle cells.

Group 15, claims 32-33, drawn to an agent identified by the screening method, that decreases or inhibits occlusion of a vessel.

Group 16, claims 32-33, drawn to an agent identified by the screening method, that decreases or inhibits vascular obstruction.

Group 17, claims 32-33, drawn to an agent identified by the screening method, that decreases or inhibits restenosis.

Group 18, claims 32-33, drawn to an agent identified by the screening method, that prevents stenosis.

Group 19, claims 36-38, drawn to a method of conducting a drug discovery business.

Group 20, claims 39-40, drawn to a method of screening to identify and/or characterize an elastin receptor.

The technical feature linking Groups 1-20 appears to be that they all relate to an agent that promotes elastin signaling.

However at the effective filing date of the present application (3/27/02), at least Keating et al (WO 00/50068; IDS) already taught the use of elastin-based compositions (e.g., elastin fibers, elastins, tropoelastins or fragments thereof) to treat vascular diseases such as atherosclerosis, restenosis, stenosis (see pages 3-5). Specifically, Keating et al disclosed that elastin-based compositions promote well-defined and well-organized actin staining of the contractile apparatus in vascular smooth muscle cells (example 5), prevent vascular restenosis in a pig model (examples 6 and 8). Furthermore, at the effective filing date of the present application, Rabinovitch, M (WO 99/433308) also taught at least the use of a serine elastase inhibitor such as elafin or L-arginine that leads to a reduction of the smooth muscle cell proliferation associated with pulmonary hypertension in a patient (see at least the abstract and page 2, second paragraph).

Therefore, the technical feature linking the inventions of Groups 1-20 does not constitute a special technical feature a defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Consequently, the claimed subject matter is restricted into the above Groups of Inventions for the following reasons.

The currently claimed subject matter (Inventions of Groups 1-20) lacks unity of invention according to Rule 13.1 PCT for the following reasons.

The methods of uses in Groups 1-7 differ one from the others because they utilize a nucleic acid (Group I), a peptide or a polypeptide or a peptidomimetic (Group 2), a small organic molecule (Group 3), an antisense oligonucleotide (Group 4), a RNAi construct (Group 5), a ribozyme (Group 6) and an antibody (Group 7), respectively, and these agents do not share the same technical feature because they are structurally and chemically different one from the others. The methods in Groups 1-7 also do not share the same technical feature as the methods in Groups 8, 19 and 20 because while the methods of Groups 1-7 are directed to treatment methods, the method of Group 8 is drawn to a screening method to identify an elastin activator, the method of Group 19 is directed to a method of conducting a drug discovery business and the method of Group 20 is drawn to a method of screening an elastin receptor having specific recited method steps and starting materials that are not required in the screening method of Group 8.

The agents in Groups 9-17 lack unity of invention one from the other because each agent in each separate group has a specific recited function and/or property that is different one from the others.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A. Additionally, should Applicants elect anyone of Groups 1-7, Applicants are further required to elect a specific function for the elected agent in the elected group from the followings:

(i) binding to and activating the elastin receptor,

(ii) increasing the expression and/or activity of tropoelastin,

(iii) increasing the expression and/or activity of a protein that activates the elastin receptor,

(iv) activating Gi,

(v) activating RhoA,

(vi) inhibiting the expression and/or activity of a protein that represses elastin signaling

This is an additional group restriction, because an agent (e.g., a nucleic acid, a small organic molecule, an antibody) having any of the specific functions listed in (i)-(vi) above lacks unity of invention one from the others because each of the above functions is different one from the others.

B. Should Applicants elect Group 2, wherein the agent is a peptide, a polypeptide or a peptidomimetic Applicants are further required to elect a specific peptide or polypeptide or peptidomimetic from the followings:

(i) elastin receptor or a constitutively active elastin receptor,

(ii) Gi or a constitutively active Gi,

(iii) Rho A or a constituitively active RhoA,

(iv) a GAP,

(v) a polypeptide comprising an amino acid sequence at least 80% identical to SEQ ID NO:2 (human tropoelastin),

(vi) a polypeptide comprising an amino acid sequence at least 80% identical to SEQ ID NO:3 (a peptidomimetic of tropoelastin),

(vii) a polypeptide comprising an amino acid sequence at least 80% identical to SEQ ID NO:6 (GTPase)

This is an additional group restriction, because each of the above agents in (i)-(vii) lacks unity of invention one from the others because each of these peptides, polypeptides or peptidomimetics is different structurally, chemically one from the others.

It has also been decided that, due to the high burden on the Office to search sequences ONE sequence constitutes a reasonable number for examination purposes. Examination will be restricted to only the one elected sequence within each elected Group. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (e.g., oligomeric probes and/or primers).

Species restriction

Should Applicants elect anyone of Groups 1-7, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. A single species recited in the Markush group of either claim 9 or claim 27.

2. A single species recited in the Markush group of claim 12.

3. A single species recited in the Markush group of claim 16.

Applicant is required, in reply to this action, **to elect a single species consistent to the elected invention** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

1. Each of the listed species of a body vessel is different physically and structurally one from the others.

2. Each of the listed species of a compound is different chemically and structurally one from the others.

3. Each of the listed species of an intraluminal device is different structurally and physically one from the others.

Each of the aforementioned species is different structurally one from the others. Each different structure can be considered to be a "special technical feature"; and therefore the listed species lack the same or corresponding special technical features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

QUANG NGUYEN, PH.D.
PRIMARY EXAMINER